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SUMMARY

Accomplished Pharmaceutical R&D leader with proven expertise in cross-functional program management, formulation development, aerosol characterization, technology innovation, department management, and focused problem solving.

PROFESSIONAL EXPERIENCE

MicroDose Therapeutx, Inc., Monmouth Junction, NJ

Jan 09 - present **Senior Director, Product Commercialization**

Direct multifunctional pharmaceutical programs through preclinical assessment, product development and clinical development.

- Head inhaled antiviral development program (MDT-637) for the treatment of RSV.
- Direct multi-million contract with US government for the development of inhaled atropine for treatment of nerve gas intoxication
- Program manager for oral treatment (MDT-006) for irritable bowel syndrome and other conditions which benefit from P2Y2 receptor activation
- Member of MDT Senior Management Team and provide technical and business evaluation of in-licensing and pipeline opportunities

MAP Pharmaceuticals, Inc., Mountain View, CA

Jan 07 - present **Director, Research and Development**

Lead multifunctional pharmaceutical development teams through formulation and aerosol product development, GMP manufacture and clinical trial product release. Responsible for executing clinical trials up to and including Phase 2a.

- Direct R&D department comprising Formulation, Drug-Device Integration, Aerosol Research, Venture Program and CMC functions.
- Member of MAP Senior Management, IP Strategy Team and Leader for Pipeline Committee.
- Set managerial objectives, team goals and timelines. Conduct performance reviews, promote professional development, ensure employee retention and high caliber hiring, and assure streamlined functioning with other departments.

Program Management

- Directed all product and clinical development for successfully completed Phase 2 studies in asthmatics (Australia), which utilized a product comprised of novel particle engineering, formulation and inhaler device technology.

- Responsible for driving new respiratory device platform through pharmaceutical development. Appointed international Scientific Advisory Board and completed n=100 user-interface clinical breathing study. Worked with market research, industrial design and engineering prototyping companies to create clinical evaluation devices, in parallel with formulation, aerosol performance and drug stability assessment.
- Led technology presentations, timeline and deliverables, leading to creation of a new alliance relationship.

R&D Strategy and Processes

- Implemented and manage stage gate process for pipeline candidate selection and lead a cross-functional pipeline committee (R&D, marketing, business development and clinical).
- Direct all external programs at Universities and Preclinical CROs engaged in formulation, pharmaceutics, synthetic chemistry and pharmacological research.
- Introduced several contingency particle processing technologies in support of Phase 3 programs to protect manufacturing supply chain.
- Inventor on several key patent applications across diverse range of technologies, and provided technical assessments of third party IP and internal patent portfolio.
- Played pivotal role in acquisition of Eiffel Technologies' particle processing technology (Australia) and negotiated a technology transfer program to Mountain View, CA.

Finance

- Managed multi-million dollar department budget to within 5% of Annual Operating Plan. Prepared yearly R&D budgets and 5-year forecasts for headcount, facilities and program costs. Managed accruals with R&D managers and finance team ensuring effective monthly closes.

MAP Pharmaceuticals, Inc., Mountain View, CA

Mar 05 - Dec 06 **Manager, New Product Development**

Managed Formulation Development, Aerosol Characterization and Analytical Chemistry teams involved in 3 major MAP Pharmaceuticals development programs

- Effectively managed rapid pharmaceutical development of inhaled insulin program through completion of clinical proof of concept (Australia). Led all aspects of particle engineering, formulation development, resolved solid-state degradation and aggregation phenomena. Partnered with PK/PD experts for clinical data analysis.
- Led DOE robustness program and commercial validation for GMP aerosol particle processing technology at contract manufacturer. Led Joint Development Committee for technology transfer to East Coast from the UK prior to technology acquisition by MAP.
- Completed scientific hiring and build out of laboratories. Attained capital approval for in-house clinical manufacturing (Class 10000 GMP clean room and processing equipment).
- Authored CMC Module 3 for IND and EOP2 package. Attended pre-IND and EOP2 meetings with FDA (Pulmonary and Allergy, and Neurology Products division).
- Submitted several worldwide patent applications on formulation, processing technology and PK profiles.

MAP Pharmaceuticals, Inc., Mountain View, CA

Jul 04 - Mar 05 **NCE Project Leader**

Fourth hire into MAP Pharmaceuticals venture-backed start up, responsible for set up and leadership of Formulation, Product Development and Analytical/QC laboratories and management of key program vendors

- Managed key formulation and final product fill/finish vendors through Phase 1 clinical supply (Nektar Therapeutics, Elan Drug Delivery, Eiffel Technologies, Exemplar Pharmaceuticals).
- Completed stability, performance optimization and container-closure compatibility studies for Phase 1 neurology product. Conducted site audit for Phase 1 EU safety and PK trial, authored technical section of IMPD, managed bioanalytical set up and validation, and provided site monitoring during trial.
- Oversaw manufacture and supply of GLP toxicology batches for chronic pulmonary toxicology programs at Battelle.

Nuffield Hospital, Brighton; The London Clinic, London; Royal Naval Hospital, Portsmouth, UK

Sept 00 - Jun 04 **Clinical Pharmacist (Part time)**

- Completed 7 months of clinical pharmacy outside of Ph.D. research. Provided pharmaceutical care of in- and out-patients. Supervised pharmacy technicians. At London Clinic, was responsible for approving in-house manufactured aseptic chemotherapy to cancer unit.

AstraZeneca R&D Charnwood, University of Leicester NHS Trust, UK

Jul 99 - Aug 00 **Preregistration Pharmacist**

- Worked in parenteral formulation development. Researched and formulated surfactant and cyclodextrin formulations of cardiovascular agent for solubility and stability enhancement.
- Commissioned technology for investigating collapse phenomena in lyophilized formulations.
- Supported Phase 1 clinical manufacture for solution formulation of Viozan® for trial use.
- Completed placements in Regulatory Affairs (competitive NDA reviews), Manufacturing (Prilosec®), Clinical Trial Supply and Pharmacovigilance.
- Held 6-month residency position in respiratory, cardiology and surgery wards. Rotated through sterile and aseptic manufacture, drug information and clinical trial supply secondments.

EDUCATION

Ph.D. **Pharmaceutics** London School of Pharmacy, University of London, 2004

- Pulmonary drug delivery technology for sustained release, AstraZeneca funded research grant.
- Broad application of drug, particle engineering, formulation and aerosol performance characterization techniques.
- Completed contract research program in ocular pharmaceutics for Allergan, Inc.
- Trained undergraduates in aseptic and sterile technologies, and small scale manufacturing

MRPharmS Licensed Pharmacist Royal Pharmaceutical Society of Great Britain, London, 2000

BPharm	1st Class	Institute of Pharmaceutical Sciences, University of Nottingham, 1999

PROFESSIONAL SOCIETIES

American Association of Pharmaceutical Scientists, American Thoracic Society, International Headache Society, American Headache Society

EMPLOYMENT STATUS

US Permanent Resident